California Department of Public Health/Office of AIDS

Hepatitis C Testing Services Guidelines, 2007

GOAL: To increase the numbers of individuals at risk for HCV who know their Hepatitis C virus (HCV) antibody status, and receive appropriate risk reduction counseling for HCV and HCV education and referrals.

I. BACKGROUND

In 2003, California Department of Public Health, Office of AIDS (CDPH/OA) conducted a demonstration project to evaluate the use of HCV testing as an incentive to attract larger numbers of injection drug users (IDUs) into HIV counseling and testing (C&T). Among the results:

- HIV testing rates among IDUs nearly doubled when HIV C&T was offered in conjunction with HCV C&T;
- HIV test disclosure return rates increased by 21 percent among IDUs when individuals were able to receive both their HCV and HIV test results; and,
- IDUs were more interested in learning their HCV status than their HIV status.

As a result of the demonstration project, CDPH/OA implemented the *Injection Drug User HIV Counseling and Testing Utilizing HCV Screening High-Risk Initiative* in 24 local health jurisdictions (LHJs). The expanded project was deemed successful, so beginning January 2008 CDPH/OA will integrate the existing HCV testing project into the restructured HIV C&T Program.

II. HEPATITIS C OVERVIEW

Hepatitis refers to inflammation, or swelling of the liver. HCV, which is spread through blood-to-blood contact, can infect a person's liver cells and may eventually lead to cirrhosis, liver cancer, and liver failure. Immediately after a person is infected with HCV, he or she enters the acute, or short-term, stage of the disease. Many people with acute infection experience no symptoms at all, and do not know that they are infected. Treatment for the disease is available; however, there is no vaccine to prevent HCV infection.

In 2000, an estimated 600,000 persons in California were chronically infected with HCV, and 5,000 people in the state are estimated to be infected each year. While 15 to 25 percent of infected individuals spontaneously clear the virus (meaning the infection has been resolved), 75-85 percent eventually develop chronic infection. Approximately 1 percent (1,000 to 1,200 persons per year in California) die as a result of HCV disease.

Hepatitis C is not spread by casual contact, such as hugging, kissing or sharing food. In the United States, most people infected with HCV have been exposed by:

- Sharing needles and other equipment used to inject substances. This is the most common way to get hepatitis C in the United States.
- Having had a blood transfusion or organ transplant before 1992. Since 1992, all donated blood and organs are screened for hepatitis C.

Some debate has occurred on the role of multiple sex partners in transmission, though recent studies of sexual transmission of HCV have indicated that the virus is spread inefficiently through this route.

III. HCV TESTING SERVICES

The following provides an overview of the HCV testing process, and describes how different aspects of HCV testing can be integrated into HIV C&T.

Client Assessment Process

Each client coming into the test site will complete the self-administered Client Assessment Questionnaire (CAQ). The responses to the following questions on the CAQ will be used to determine whether or not an HCV test is offered:

19. Has a medical or service provider ever told you that have hepatitis C?
20. Have you ever used a needle to inject drugs?

If the client answers “yes” to question 19, then he or she should **not** be offered an HCV test. The counselor should confirm with the client that he or she is connected with HCV support and care, as appropriate.

If the client answers “no” to question 19, but “yes” to question 20 then he or she may be offered an HCV test. Clients who hay have shared equipment to inject hormones, vitamins or steroids and do not know their HCV status may also be offered an HCV test.

Clients are not required to take an HIV test in order to receive an HCV test.

While the CAQ form is used for the client to self-identify their risk for HCV, documentation of the HCV or HIV/HCV C&T service will be on the HIV Counseling Information Form (CIF). See Reporting Requirements on page nine.

HCV/HIV Counseling Session

The decision on which service to offer the client, either the HCV counseling session or the combination HCV/HIV counseling session, is based on the risk level of the client as established by the CAQ process

listed above. Only a Counselor II may provide HCV counseling sessions, as a higher skill level is required due to the complexity of the session.

HIV Low Risk/HCV High-Risk

If the client is only at risk for HCV, then the client does **not** have to be provided with a comprehensive counseling session that covers both HIV and HCV. In the counseling session:

- Discuss with client risk reduction and harm reduction strategies in order to prevent further exposure to HCV;
- Reinforce existing behaviors that maintain negative status;
- Discuss with client what an HCV positive result means, and how that is that different from HIV;
- If client is already HCV positive, discuss recommendations to seek further testing from a physician to determine health status.

HIV High-Risk/HCV High-Risk

For those clients at risk for both HIV and HCV, one comprehensive counseling session should address both disease risks. In the counseling session::

- Reinforce HIV prevention through HCV prevention messages;
- Discuss risk reduction and harm reduction strategies in order to prevent continued exposure to HIV and HCV;
- Discuss the differences between an HIV positive versus an HCV positive test result;
- Discuss relapse, if applicable; and,
- Discuss co-infection issues, if applicable.

Reviewing Possible Test Results

The meaning of the possible test results should be reviewed with the client. Screening for antibodies to HCV (anti-HCV) is the first step in identifying people living with HCV. If antibodies are found, a second test, called a Nucleic Acid Test (NAT), that looks for the virus itself should be used to confirm current infection. CDPH/OA funds screening for HCV antibodies and referral to medical providers for confirmatory testing.

A “negative” result means that antibodies were not detected in the blood sample. This means either the person is not infected with HCV or, if they had a recent exposure, that they are infected but not enough time has passed for antibodies to be detectable on the test (the window period).

A “positive” result means that antibodies to HCV were detected and the client needs supplemental testing to determine if they are infected with HCV or have resolved the infection. With the Home Access kit, a positive

EIA is repeated two more times, and a RIBA is performed to minimize the chance of false-positive results.

An “indeterminate” result means the laboratory was unable to determine if the test result was positive or negative and another sample should be collected and tested to determine anti-HCV status.

Window Period

There is an amount of time after HCV infection occurs before antibodies are detectable by the EIA. The average window period for anti-HCV is eight to nine weeks. Ninety percent of people have developed antibodies after three months, and 97 percent of people have detectable levels of antibodies six months after infection.

Obtaining Informed Consent for HCV Testing

While specific written consent is not required under California law when providing an HCV test, some LHJs may feel that written consent is appropriate or, at the very least, will document verbal consent in some manner. OA recommends documenting verbal consent.

Some LHJs that have implemented specific written consent for HCV testing have used the form as an opportunity to deliver additional information on HCV testing, such as what the result means, and to gather information that can be used to locate the client if they do not return for their results disclosure session.

Prior to implementing HCV testing, each LHJ should determine whether verbal or written consent will be required and how the consent will be documented. If written consent is used for HCV, the consent form should be linguistically appropriate.

HCV Testing Options

LHJs may choose which type(s) of HCV test will be offered to clients. Two types of HCV testing are available: the Home Access test kit or testing through a laboratory, whether county, state or independent. It is up to each LHJ to determine which test will be used.

The decision regarding which testing option is chosen should be based on a number of factors affecting clinic services, such as: availability of phlebotomists; clients’ preference for fingerstick (Home Access), and the type of HIV testing already being offered at the clinic. Some LHJs may choose to offer rapid HIV testing with a standard HCV test (blood draw) or the Home Access kit. Others may choose to use the conventional HIV test with either a standard HCV or the Home Access kit.

Standard Blood Draw

A blood sample is collected by a licensed phlebotomist and sent to a laboratory for processing.

Choosing a Laboratory/Laboratory Slips

LHJs may choose to use a county, state or private laboratory to process the blood samples. CDPH/OA does not provide laboratory slips for the HCV program: LHJs must use the forms provided by the laboratory they select to process the HCV test.

Self-administered Home Access Test kit

The Home Access test kit checks the blood specimen for Hepatitis C antibodies. The test shows whether a person has ever contracted HCV. It does not show whether the infection is active. This must be determined by a physician with additional testing.

The sample collection method is a client self-administered fingerstick, whereby the blood drop is placed on filter paper. If an LHJ chooses to use the Home Access test kit, the coordinator will be responsible for training staff on the test kit process. See Appendix A for the *Protocol for Using the Home Access Hepatitis C Test Kit*.

Obtaining Test Kits

Each LJH that opts to use the Home Access kits is responsible for obtaining testing kits from the manufacturer, Home Access Health Corporation. LHJs will need to purchase the kits required through a county purchase order. The Home Access representative for purchases is:

Marisol Delgado
Phone: (847) 781-2504
Fax: (847) 839-3326
Email: mdelgado@homeaccess.com

A Note about Clinic Flow

Clinic flow processes should be determined locally, however, CDPH/OA recommends that LHJs provide a comprehensive risk reduction counseling session that covers both HIV and HCV if the client is at risk for both. Prior experience indicates that streamlined approaches, in which both topics are addressed in one counseling session, benefit both the test site and the client. The flow of the testing will be determined by which testing devices are used for HCV and HIV, if an HIV test is also being administered.

Disclosure of Test Results

If the test site is using conventional HIV testing, the result disclosure date should be set so both results may be given in the same session if the client took both an HIV and HCV test. The time for setting the disclosure date will vary by LHJ, based on laboratory processing time. Typically the time allowed for is two to three weeks.

Disclosure Session

Face to face disclosure is recommended as the preferable disclosure method. The disclosure session for giving HCV negative results may be conducted by a Counselor I or Counselor II. The disclosure session for giving HCV positive results must be conducted by a Counselor II.

If the HCV test result is negative:

- Discuss with client what the result means, including information about the window period;
- Reinforce existing behaviors that reduce risk of transmission;
- Discuss safer injection practices, if appropriate; and,
- Provide referral to support services for further counseling, information or materials that reduce risk.

If the client is HCV antibody-positive:

- Discuss with client what the result means;
- Reinforce existing behaviors that reduce risk of transmission;
- Discuss safer injection practices, if appropriate;
- Provide referral to support services for further counseling, information or materials that reduce risk;
- Discuss recommendation to seek further testing from a physician to determine health status;
- Discuss the differences between an HIV positive and an HCV positive test result;
- Discuss disclosure of test result to needle-sharing partners; and,
- If applicable, discuss co-infection issues.

No-Show Follow-up

If a client who received a confidential test does not return for their result, conduct follow-up in order to get the client to return for their test result.

An HCV negative result may be given to the client if it is within 60 days of the date of the test. Clients returning for their result *after* 60 days from the date of their HCV test must be re-tested. An HCV positive result may be given to the client at any time. However, the record must be updated and key entered into the Local Evaluation Online (LEO) reporting system prior to the end of the fiscal year.

Utilizing the Home Access PIN Number

Each Home Access kit comes with a processing code. Protocol for establishing a return date must be set by the LHJ based on the type of clinic or venue. If a conventional HIV test is provided, it is preferable to set the return date to coincide with the HIV result processing time so that both results can be given in the same disclosure session.

To obtain HCV test results, clients may return to the test site to have results disclosed by a counselor, or they may call the manufacturers' hotline to receive their test result by phone. While CDPH/OA would like clients to return to the test site for face-to-face disclosure of the result, best practices for results disclosure should not override the clients' need to learn their HCV status. Some LHJs may choose to allow the clients to call Home Access to obtain their results themselves. If this is done, the LHJ staff should also access the results and follow up with the client to discuss the results and provide appropriate referrals.

Referrals/Linkages to Care

An important part of the HCV testing process is the provision of appropriate referrals and linkages to care, when applicable. Each LHJ should develop a list of resources that can be provided to clients testing for HCV. Some of the referrals will be very similar to those already given to IDUs who test for HIV. What may be new are referrals for further testing and follow-up medical care for clients that test HCV positive. If the client has also tested positive for HIV, then the client should be encouraged to share the HCV test results with their primary medical provider who will be handling their HIV medical care.

For those who are HCV-positive and HIV-negative, specific referrals for further HCV testing and follow-up medical care need to be developed. Possible referrals include HCV support groups, medical providers who specialize in HCV, and appropriate educational materials that discuss HCV and liver health. In some LHJs it may be difficult to identify entities that can provide HCV medical care for those who are uninsured, or under-insured. It is important to keep in mind that individuals can do a great deal to assist with the health of their liver by making lifestyle changes, such as reducing alcohol intake and exercising.

IV. Funding and Reimbursement

All LHJs have previously received a funding letter with their HCV program allocations listed. The reimbursement for each LHJ is funded as a block grant and each contractor must provide services based on the performance standards as outlined in the scope of work portion of this guidance.

The timelines for invoice submission are the same as the requirements for progress reports as noted in the scope of work section listed below. Please note

that although HCV services are documented on a CIF and entered into the LEO system, the computer program will not automatically generate an invoice for any HCV services. Since HCV services (neither HCV only nor the HCV part of the combined HCV/HIV counseling session) are not invoiced through LEO, a manual invoice must be created and submitted by the LHJ on a quarterly basis. Each quarter LHJs should invoice CDPH/OA for services and operating expenses as specified in the five-line item budget and budget justification that was a submitted. The invoice should include any amount that was spent to purchase the Home Access test kits, other testing supplies and laboratory expenses.

V. Staffing and Training

Only CDPH/OA certified HIV Counselor II staff (including counselors certified prior to January 1, 2008) are able to provide this intervention.

All staff providing HCV services should be knowledgeable and adequately trained to deal with the client issues that may arise in testing for HCV. Many of the issues and concerns raised in an HCV testing session are similar to those raised in a HIV counseling session with clients who have similar risk profiles. Currently there is a Hepatitis C continuing education training available for HIV counselors, and CDPH/OA is assessing the need for additional Hep C trainings for counselors. Any additional training requirements and updates will be provided by CDPH/OA as HCV integration is phased in and implemented in LHJs.

The California STD Control Branch maintains an Adult Viral Hepatitis Prevention Coordinator (formerly the California Hepatitis C Coordinator). This staff member can assist the LHJs in identifying additional training and resources as needed. The Adult Viral Hepatitis Prevention Coordinator can be reached at (510) 625-6000.

Free materials, including brochures, posters and videos aimed at both client and staff education are available at the Oasis Clinic web site:

http://www.oasisclinic.org/8_BOOKS_VIDEOS.html

Free training for staff, as well as free materials for both patient and staff education, is available at the HCV Advocate web site:

http://www.hcvadvocate.org/

Additional information about HCV can be obtained at the Centers for Disease Control and Prevention web site: http://www.cdc.gov/ncidod/diseases/hepatitis/c/

VI. Scope of Work

Performance standards

A progress report must be submitted to the state on a quarterly basis for the first two years of the contract and twice a year for the remaining year of the contract

period. The information must be submitted thirty days after the end of the quarter. The reporting dates for submitting the progress reports are the same as the invoicing requirement for the first two years of the contract. The schedule is as follows:

1st quarter – October 30th
2nd quarter – January 30th
3rd quarter – April 30th
4th quarter – July 30th

In the third year of the contract, invoicing will remain quarterly, but progress reports will be due semi-annually.

Performance Measures

For LHJs which will be conducting HCV testing, the following performance measures will serve as guidelines for service design, delivery and evaluation. CDPH/OA requests that each LHJ submit a one-page document outlining how the performance measures will be met.

1. Seventy-five percent of IDUs of unknown or negative HCV antibody status at select sites (to be determined by the LHJ in consultation with CDPH/OA) will be offered an HCV test.

   Of those electing to test, 75 percent will receive their results.

2. Ninety percent of those testing HCV positive will receive appropriate referrals for follow-up support and care.

3. Eighty percent of the services provided will be a combination HIV/HCV risk reduction counseling session.

4. LHJs will annually update a resource guide that will be used to reach potential clients who are at risk for HCV.

5. LHJs will annually update a list of referrals for clients who are at risk for HCV and clients who test HCV positive.

6. LHJs will comply with the LEO system reporting requirements for data submission.

7. LHJs will ensure that staff is adequately trained to offer HCV services.

For LHJs which are minimally funded under this initiative, there are no reporting requirements. However, each LHJ is required to update its referral guide to include HCV testing and treatment resources for HCV-infected and at-risk clients.

VII. Reporting Requirements

Documentation of Services

The counselor will complete a CIF to document HCV counseling, testing and referrals for both the HIV/HCV combined service and the HCV testing only service. HCV risk assessment and testing information is located on the back of the CIF. The CIF information must be entered into the LEO system even though the HCV services are not invoiced through LEO.
Important: While the CAQ is the initial form used in the process of identifying, counseling and testing clients at risk for HCV **only,** the CIF document is used to document services in LEO. Each LHJ should retain the CAQ for audit purposes. Staff should not key enter a CAQ for a client who also had a CIF completed, since all information on the CAQ is included on the CIF when counselors provide the risk reduction counseling session. It is important to remember that the LEO system can only accept one "OA ID Number" for either the CAQ or CIF form.

Tracking

For HCV-only services, a white sticker must be placed on the CIF in the unique Office of AIDS Client Number box in the upper right hand corner of the form. When both HIV and HCV testing occurs, staff must place one of the stickers from the OA laboratory form on both the CIF and the HCV laboratory slip. The LEO system will enable both the LHJ and CDPH/OA to generate reports to monitor the services provided, demographic information, return rates and positivity.

Appendix A: Protocol for Using the Home Access Hepatitis C Test Kit

The Home Access Hepatitis C Test kits are FDA approved for ages 18 and older and were designed to be a self-administered home test. Home Access has a modified program for implementation in clinic and community based settings. Home Access will never have access to a client's name, as only the Personal Identification Number (PIN) is used to identify clients.

1. Gather Supplies and prepare forms. You may want to prepare these materials ahead of time – especially if you anticipate conducting multiple tests in a row.

Hepatitis C Check Kit:	*Additional items:*	*Forms needed:*
Blood sample card (with detachable PIN)	Extra bandaids	Home Access fax cover sheet
Sample pouch with desiccant (foil)	Latex gloves (2 pairs)	Home Access PIN tracking form
Self-addressed mailer (cardboard)	Paper towel	
Lancets (2)	Surface protectors	
Gauze and Bandaid	Biohazardous waste container	
Alcohol preparation pad	Bleach	

Optional: To minimize errors in transcribing PINs, you may want to create three labels marked with the same PIN as the blood sample card ahead of time. The PIN is put on the three forms needed for HCV testing: the PIN tracking form, the Informed Consent form and Counselor Information Form.

2. Write date on sample collection card and detach the yellow PIN portion and give to client. Home Access will not process a sample without a sample collection date on it. Make sure you do this step before collecting the sample to avoid possible blood exposure.

3. Support client in getting prepared to collect sample. Preparation is the key to getting a testable blood sample. There are three important things that will increase the blood flow to the area: warmth, movement and keeping the hand above the heart. If possible, run hands under warm water or rub hands together for at least 30 seconds. Shake hand back and forth and, if possible, have client stand to collect sample (if not standing, try to keep hand above heart). Make sure client does not shake or move hand after the finger has been punctured.

4. Have client puncture finger. After client has increased blood flow to the area, wipe the side of the middle or ring finger with alcohol (you should be wearing gloves). After it has dried, place the lancet (blue side up) on a clean surface and have client place cleaned finger above hole in the middle of lancet. Ask client to press VERY firmly down over the hole until it punctures finger. Unless you are a trained phlebotomist, you cannot help client puncture finger.

5. Collect blood sample. Once finger is punctured, have client squeeze base of finger, moving towards puncture site. Be careful not to restrict blood flow. Make sure the finger DOES NOT touch the sample collection card in any way as this can contaminate sample. Instead, have the bottom of the blood droplet touch the sample card. Make sure the blood completely covers the entire circle on the sample card. If the person stops bleeding, use the gauze to wipe the puncture site to remove clotting. If this doesn't yield enough blood, client may have to use another lancet on same or different finger.

6. Bandage finger(s). If client is still bleeding, he or she should apply gentle pressure to puncture site.

7. Dispose of waste. A biohazard bag is appropriate for all materials (the lancet is placed in a self-contained sharps container and can only be used once.)

8. Place sample collection card in foil pouch and place pouch in cardboard mailer.

9. Mail sample and Fax PIN to Home Access.